IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO ALL PLAINTIFFS LISTED IN EXHIBIT "A" TO THE INITIAL MOTION	

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF CHRISTINA PRAMUDJI, MD

PRELIMINARY STATEMENT

Defendants' opposition to the *Daubert* motion to preclude Dr. Pramudji from offering opinions regarding adequacy of warnings suggests that Dr. Pramudji should be permitted to offer these opinions based solely on her qualifications as a urogynecologist. But Plaintiffs' motion is not based on lack of qualifications, but rather lack of reliability. The deficiency in Dr. Pramudji's warnings opinions is that she did not consider or consult **any** standard whatsoever, leaving her opinion devoid of any verifiable methodology.

Similarly, the Defendants attempt to preserve Dr. Pramudji's opinions regarding the design of the subject devices, despite her lack of qualifications, as well as the absence of reliance on any objective, articulable standard in that area. Defendants instead substitute a literature review and her personal use of the product, in an attempt to make up for the lack of her qualifications and reliable methodology in this area. Finally, Defendants mischaracterize Plaintiffs' motion with regard to Dr. Pramudji's degradation opinions. Plaintiffs seek the same ruling as was issued in *Huskey*: that Dr. Pramudji is permitted to offer opinions regarding what

she has seen in clinical practice with regard to degradation, but she is not qualified to offer opinions on chemical degradation of polypropylene beyond what she has observed in her practice.

LEGAL ARGUMENT

A. Dr. Pramudji failed to apply any objective, reliable standard in offering her warning opinions, in violation of *Daubert*.

Plaintiff does not take issue on this motion with Dr. Pramudji's credentials. Rather, plaintiff's claim is that Dr. Pramudji's opinions are entirely subjective, without reference to any standard. The opposition brief fails to identify any standard or methodology applied by Dr. Pramudji, or any standard by which Dr. Pramudji's opinions on the warnings can be objectively evaluated. That gap is fatal to Dr. Pramudji's warning opinions. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D.W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *32. The same applies to Dr. Pramudji, who did not even know the purpose of the IFU. (Dr. Pramudji 9/17/14 Dep. Tr. at 78:15-21, attached as Exhibit A). Fatal to her opinion, Dr. Pramudji admitted that she did not know or "rely on any internal standards or any deposition testimony by any Ethicon witness as to what information needed to be in the IFU." (*Id.* at 17:6-19).

The Defendants' fallback position is that Dr. Pramudji should be permitted to testify that the risks of the mesh products were obvious to surgeons, and therefore the jury can find that there was no duty to warn at all. This transparent effort to justify the expert's deficient methodology is of no avail. Dr. Pramudji has performed no reliable or verifiable study or analysis of what surgeons may or may not know, in order to support a valid opinion that a

warning was not necessary on any particular issue. We simply have Dr. Pramudji's say so, which is insufficient under *Daubert*. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 157 (1999) (stating that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert").

The Defendants and their experts apparently realize that the warnings are utterly deficient when evaluated under the proper standards. So, they take the unverifiable position that pelvic surgeons know of certain risks, thereby obviating the need to warn. (Defense Brief at 5-7). However, Dr. Pramudji admitted she lacked any foundation to opine as to what surgeons generally knew about the risks of pelvic surgery with mesh:

> Q. So simply saying that doctors would understand something or know something, you -- leaves questions as to what different doctors know. Let me rephrase it. You don't know the level of experience and knowledge of each doctor that considered using the Prolift. You haven't studied that question, right?
>
> A. No. That would be impossible to know.
>
> Q. And in providing warnings and information, you wouldn't want to assume that all physicians would have the same level of knowledge and experience as you would have, right?
>
> A. Well, I think the IFU clearly states that it's designed for pelvic surgeons that are familiar with the pelvic -- with pelvic surgery. So I think we're starting with a baseline knowledge.
>
> Q. Okay. Familiar with pelvic surgery with mesh. How many surgeries does that mean? Is there a defined number?
>
> A. No, there's not a defined number.
>
> Q. A doctor could do one procedure with mesh and think that he or she is familiar with that type of surgery, correct?
>
> A. I suppose a doctor could assume that. Yeah, some -- some doctors –

> Q. So saying that doctors need to be familiar with surgery with mesh really doesn't tell you anything about the level of knowledge and experience the doctor needs to have, correct?
>
> A. I mean, you're -- it's common sense basically that if there's a -- if you go through training and you have been trained on pelvic surgery in residency or after fellowship, then -- then you have a knowledge of pelvic surgery. I mean, it's obvious common sense that if you just do one that you're not familiar with it whether a doctor thinks that or not.
>
> Q. Telling doctors that they need to be familiar with pelvic surgery does not tell the doctor specifically what their level of knowledge and experience needs to be. It's not defined, correct?
>
> A. Yes. It's not defined. It's not specific. You're correct.

(Dr. Pramudji 9/17/14 Dep. Tr. at 82:22-84:12, Exhibit A). That testimony makes it clear that the defense expert cannot testify that risks were known to doctors without being warned. In fact, her statement that this is a matter of "common sense" takes the issue completely out of the realm of expert testimony.

In addition, this opinion is directly contradicted by the deposition testimony of various Ethicon employees. For example, Charlotte Owens testified that the IFU needed to "clearly and unambiguously communicate" necessary warnings, and they **"need[] to list each of the adverse reactions that were known to you in Medical Affairs."** (Charlotte Owens Dep. Tr. at 262:7-13, 309:23-310:3, attached as Exhibit B) (emphasis added). Similarly, David Robinson of Medical Affairs testified that the IFU **"should accurately represent what we knew to be risks,"** and that a complication would need to be listed if it had **"a frequency or a severity that had some implication for a risk/benefit ratio."** (David Robinson Dep. Tr. at 488:11-18, 489:4-10, 492:23-493:8, attached as Exhibit C) (emphasis added). Finally, Dr. James Hart, Chief Medical Officer of the Johnson & Johnson Global Surgery Group, testified that the purpose of the IFU is to:

> **provide a COMPLETE STATEMENT of what the company knows with regard to the indications, the contraindications, the warnings, the precautions and the adverse reactions for the device.**

(Dr. James Hart 12/20/13 Dep. Tr. at 800:3-8, attached as Exhibit D) (emphasis added).

The deposition testimony of Sean O'Bryan of regulatory affairs confirmed that Ethicon could not withhold warnings based on an assumption that surgeons would otherwise know the risks:

> Q: When you worked on that project, it was your understanding from an FDA regulatory perspective it would not be legitimate to not include warnings of potentially significant adverse events based on a decision that the surgeons would figure that out on their own?
>
> A: No, that's correct.

(Sean O'Bryan 5/18/12 Dep. Tr. at 107:14-21, attached as Exhibit E). This testimony invalidates the subjective, unsupported position by Dr. Pramudji that would allow Ethicon to fail to warn based on an unverifiable claim or assumption that physicians would know the risks without being warned. Of course, that is not a standard; rather, it is an unverifiable excuse created to explain the failure to provide warnings in accordance with the applicable standards.

B. Dr. Pramudji is not qualified to give opinions on the design of the mesh products, has relied on no objective standard in reaching her conclusions, and her opinions should be excluded.

Dr. Pramudji is admittedly not an expert in design, and her only design opinion is based on the feel of the device in her hands, and on patient results. (Plaintiffs' Brief at 9-10). Dr. Pramudji's use of mesh products does not, by itself, qualify her to opine regarding their design any more than a person is qualified to opine about a chair based on how it feels when she sits in it, and based on what she has observed when others sit in it. Defendants claim that the foundation of Dr. Pramudji's design opinions is her "extensive review of the medical literature as set forth throughout her reports." (Defense Brief at 13). A review of the literature does not

provide sufficient basis for Dr. Pramudji to offer a reliable design opinion unless she can identify an appropriate standard that she applied. *See Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *14 (S.D. W. Va. Apr. 24, 2015) (finding that Dr. Schull had not reliably applied the principles learned through his experience and the literature to the facts of this case because he had not seen any standard operating procedures or design protocols for the development of the medical device in question).

Defendants argue that Plaintiffs have created a straw man regarding Dr. Pramudji by discussing certain Ethicon documents like design failure modes analysis, process, failure modes analysis, and failure modes effects analysis. (Defense Brief at 14, citing Plaintiffs' Memorandum at 9-12). But Plaintiffs were simply trying to ascertain what design standards Dr. Pramudji is relying on for her opinions. Nowhere do Defendants identify any standard or methodology applied by Dr. Pramudji, or by which Dr. Pramudji's opinions on the design of the product can be tested or objectively evaluated. As such, she should be precluded from giving any opinions related to the adequacy of the design of the mesh products.

C. Dr. Pramudji's should be precluded from giving any opinions regarding mesh degradation beyond testifying whether she has observed mesh degradation in her clinical practice.

Defendants misconstrue Plaintiffs' motion to preclude certain opinions of Dr. Pramudji with regard to mesh degradation. In the *Huskey* case, Defendants initially offered Dr. Pramudji as an expert on chemical degradation of polypropylene, but this opinion was withdrawn, reserving the right to call Dr. Pramudji to testify whether she has observed degradation in her clinical practice. (*See* Notice of Withdrawal of Certain Expert Ops. of Dr. Christina Pramudji and Dr. Wenzin Zheng [Docket 267] Case 2:12-cv-05201). Because the designation was withdrawn, this Court has never issued an opinion regarding Dr. Pramudji's qualifications to

testify on chemical degradation of polypropylene. Plaintiffs believe Dr. Pramudji should be precluded from testifying on that topic for the reasons stated in their initial memorandum and tacitly acknowledged by Defendants' withdraw of certain opinions in the *Huskey* case. This Court has previously ruled that Dr. Pramudji is qualified by her medical experience to testify whether or not she has observed mesh degradation in her clinical practice. *Huskey v. Ethicon*, 29 F. Supp. 3d 691, 726-27 (S.D West Virginia 2014). Plaintiffs are not seeking reconsideration, only to prevent Dr. Pramudji from expanding this opinion into other areas where she lacks qualifications such as chemical degradation of polypropylene. As such, Dr. Pramudji should be precluded from opining about mesh degradation, beyond testifying whether she has observed mesh degradation in her clinical practice**.**

CONCLUSION

For the foregoing reasons, Dr. Pramudji's opinions should be limited at trial.

Dated: May 16, 2016

Respectfully submitted,

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CERTIFICATE OF SERCE

I hereby certify that I filed the foregoing document on May 16, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Thomas P. Cartmell
Attorney for Plaintiffs

Exhibit A

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

- - -

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	MASTER FILE NO. 2:12-MD-02327
	:	NO. 2327
THIS DOCUMENT RELATES TO: DIANNE M. BELLEW,	:	CASE NO. 2:13-CV-22473

- - -

September 17, 2014

- - -

Videotaped deposition of CHRISTINA K. PRAMUDJI, M.D., taken pursuant to notice, was held at the Westin Galleria, 5060 West Alabama, Street, Houston, Texas, beginning at 10:24 a.m., on the above date, before Mary Kay Hendricks, CSR, a Registered Professional Reporter, Certified Shorthand Reporter.

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the FDA that specify what type of information is supposed to be found in warnings for the products like the Prolift, correct?

MR. SNELL: Form.

A. No, I'm not.

Q. (BY MR. SLATER) You're not familiar with the internal standards at Ethicon that the medical affairs and regulatory affairs people followed in terms of what information needed to be in the IFU and the patient brochure and other documents about the Prolift, correct?

A. That's correct. I don't know that.

Q. In drawing (sic) your opinions, you did not rely on any internal standards or any deposition testimony by any Ethicon witness as to what information needed to be in the IFU, the patient brochure or any other document about the Prolift, correct?

MR. SNELL: Form.

A. I don't -- I don't believe I did, not that I can recall off the top of my head, no.

Q. (BY MR. SLATER) You do not know what the requirements were that Ethicon had to satisfy before they could market the Prolift, do you?

A. No, I don't.

Q. You do not know what was considered by the Ethicon medical affairs director at the time that she

Q. (BY MR. SLATER) If Ethicon misrepresented information in the patient brochure, you would criticize that, right?

A. Yes.

Q. You would criticize that because that would be misleading to doctors and patients, correct?

MR. SNELL: Form.

A. Correct.

Q. (BY MR. SLATER) And you would criticize that because that could have an impact on patients' safety, correct?

MR. SNELL: Form.

A. It could have -- it could have an impact on patient safety, yes.

Q. (BY MR. SLATER) Do you know what the purpose of the IFU is from the perspective of Ethicon?

A. From the perspective of Ethicon, no. I have my perspective as a surgeon.

Q. Do you know what the purpose of the IFU is pursuant to FDA regulations?

A. No.

Q. Do you know the standards that apply to what information is supposed to be in the patient brochure?

A. No, I don't.

Q. Do you know what FDA regulations would require

you would want to have known that, correct?

MR. SNELL: Form.

A. I mean, I don't -- I mean, they did provide some guidance to that, and a lot of it was intuitive surgical principles. So I don't know that they would have added anything to -- to what I would have done, my decision making, how I used the product.

MR. SLATER: Move to strike --

A. So I would say "no." The answer would be "no."

MR. SLATER: Okay. Move to strike.

Q. (BY MR. SLATER) If Ethicon thought that there were certain women as to whom caution needed to be shown based on information that Ethicon had, would you have wanted them to share that information so you could consider it?

MR. SNELL: Form.

A. Yes, I would.

Q. (BY MR. SLATER) Your level of knowledge and experience would not be the same as all physicians considering using the Prolift, correct?

A. That's correct.

Q. So simply saying that doctors would understand something or know something, you -- leaves questions as to what different doctors know. Let me rephrase it. You don't know the level of experience and knowledge of

each doctor that considered using the Prolift. You haven't studied that question, right?

A. No. That would be impossible to know.

Q. And in providing warnings and information, you wouldn't want to assume that all physicians would have the same level of knowledge and experience as you would have, right?

A. Well, I think the IFU clearly states that it's designed for pelvic surgeons that are familiar with the pelvic -- with pelvic surgery. So I think we're starting with a baseline knowledge.

Q. Okay. Familiar with pelvic surgery with mesh. How many surgeries does that mean? Is there a defined number?

A. No, there's not a defined number.

Q. A doctor could do one procedure with mesh and think that he or she is familiar with that type of surgery, correct?

A. I suppose a doctor could assume that. Yeah, some -- some doctors --

Q. So saying that doctors need to be familiar with surgery with mesh really doesn't tell you anything about the level of knowledge and experience the doctor needs to have, correct?

A. I mean, you're -- it's common sense basically

that if there's a -- if you go through training and you have been trained on pelvic surgery in residency or after fellowship, then -- then you have a knowledge of pelvic surgery. I mean, it's obvious common sense that if you just do one that you're not familiar with it whether a doctor thinks that or not.

Q. Telling doctors that they need to be familiar with pelvic surgery does not tell the doctor specifically what their level of knowledge and experience needs to be. It's not defined, correct?

A. Yes. It's not defined. It's not specific. You're correct.

Q. And, in fact, sales representatives are paid more money when they can get more doctors in their territory interested in using a product and procedure like the Prolift, right?

MR. SNELL: Form.

A. I don't know how they're paid.

Q. (BY MR. SLATER) Well, I think you assume that sales representatives get more money based on generally more sales from the doctors and facilities in their territory. Okay --

A. Okay. I'll grant you that.

Q. That would give the sales representatives an incentive to bring doctors in for training regardless of

Exhibit B

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IN RE:	:SUPERIOR COURT OF
PELVIC MESH/GYNECARE	:NEW JERSEY
LITIGATION	:LAW DIVISION -
	:ATLANTIC COUNTY
	:
	:MASTER CASE 6341-10
	:
	:CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

- - -

September 12, 2012

- - -

Volume I of the transcript of the Deposition of CHARLOTTE OWENS, M.D., called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure, by and before JoRita B. Meyer, a Certified Realtime Reporter, Registered Merit Reporter, and Certified Court Reporter for the State of Georgia, at the offices of Troutman Sanders, 600 Peachtree Street Northeast, Atlanta, Georgia, commencing at 9:39 a.m.

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decide if they want to learn more about the system, and ultimately will use their training, education, and experience, plus this document, to decide if they want to use it.

BY MR. SLATER:

Q. Did you understand that it was necessary to clearly and unambiguously communicate all necessary contraindications, warnings and precautions, and adverse reactions to physicians through the IFU?

A. I understand the document should be clear and unambiguous, yes.

Q. Did you understand that it was necessary for Gynecare, to the extent that a risk was understood to exist with the PROLIFT, to communicate it in the IFU as opposed to assuming that surgeons would figure out that risk on their own?

A. I don't think you're giving surgeons enough credit. Surgeons don't have to figure out the complications of an area that they operate. Surgeons are trained to know the complications of the area in which they operate.

BY MR. SLATER:

Q. Does it mean too much tension?

A. It's not that simple.

Q. How would a surgeon doing the procedure be able to objectively verify, based on an objective standard, that they had placed or not placed the mesh with excessive tension?

A. They would be able to look at the repair after surgery and see if it looks relaxed or see if it looks like it's under tension.

Q. So that's how they would do it?

A. That's generally how it was done.

Q. Did you ever perform the PROLIFT procedure?

A. On the cadavers, yes. In live people, because I was not practicing during my tenure at Ethicon, no.

Q. Did you ever on your own, without any other surgeon performing the procedure -- did you ever place Gynemesh in a human's body?

A. No.

Q. Look at the adverse reactions, please. It was your understanding that you needed to list each of the adverse reactions

that were known to you in Medical Affairs in this section, correct?

A. Yes.

Q. And you understood that if you failed to list adverse reactions that you were aware of, that that would render that warning deficient to some extent, correct?

A. Deficient?

MR. BROWN: Objection.

THE WITNESS: I would say that we listed the adverse reactions that we knew were adequate and sufficient for this document.

BY MR. SLATER:

Q. Well, you just said a moment ago you agreed with me that you understood you were supposed to list each of the adverse reactions that you in Medical Affairs knew existed at the time of launch, correct?

A. We listed the adverse events that we knew to be directly related to the information that we had at this time.

Q. Okay. Were there risks -- well, rephrase.

You see where it says, at the end of

Exhibit C

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IN RE: PELVIC MESH/GYNECARE LITIGATION	:SUPERIOR COURT OF :NEW JERSEY :LAW DIVISION - :ATLANTIC COUNTY : :MASTER CASE 6341-10 : :CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

- - -

March 14, 2012

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Transcript of the continued deposition of DAVID B. ROBINSON, MD, called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Ann Marie Mitchell, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter, Certified Court Reporter, and Notary Public for the State of New Jersey, at the offices of Riker Danzig Scherer Hyland & Perretti LLP, Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, commencing at 9:35 a.m.

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director in Ethicon, you did not expect physicians to rely upon the IFU for the Prolift® as an accurate disclosure of the risks associated with the Prolift® system?

MR. GAGE: Objection.

THE WITNESS: No. I think what I said is I didn't -- they shouldn't depend on it as the sole source of their information regarding the Prolift® system.

BY MR. SLATER:

Q. My question is this: Did you expect surgeons who were considering using the Prolift® to rely upon the Prolift® IFU to accurately disclose the risks associated with the use of the Prolift® system?

MR. GAGE: Objection.

THE WITNESS: We should accurately represent what we knew to be risks at the time, yes.

BY MR. SLATER:

Q. You knew that was required by federal law. Right?

MR. GAGE: Objection.

BY MR. SLATER:

Q. By the FDA. Right?

MR. GAGE: Objection.

THE WITNESS: Actually, I don't know whether the FDA -- that is a regulatory decision.

BY MR. SLATER:

Q. And you felt that was your obligation to physicians so they would know what the potential adverse reactions were if they used that product. Right?

MR. GAGE: Objection.

THE WITNESS: To the best of our knowledge at the time, yes.

BY MR. SLATER:

Q. And if Ethicon had knowledge of an adverse reaction and did not include it in the Prolift® IFU, then the IFU would be deficient to that extent. Right?

MR. GAGE: Objection.

THE WITNESS: No, that's not true.

BY MR. SLATER:

Q. Okay.

A. Because --

Q. So let me understand this.

MR. GAGE: The witness would like to finish his answer.

MR. SLATER: He just said no. That's all I was asking.

Q. Well, I'm asking you, based on your participation in the process at Ethicon, would that be incorrect?

MR. GAGE: Objection.

THE WITNESS: I don't remember ever being asked to give the -- a final decision about adverse events being put in an IFU.

BY MR. SLATER:

Q. Let me understand this. Ethicon understood it was expected to put all of the adverse events into the IFU. However, if Ethicon failed to list -- I'm going to ask the question differently.

If Ethicon determined an adverse reaction to be material, meaning it doesn't just happen, you know, so infrequently that you don't have to consider it but it happens enough that you can actually put a percentage on it --

A. Well --

MR. GAGE: Let him finish his question.

BY MR. SLATER:

Q. Let me ask you this.

How would you define a complication to be material enough that it would need to be listed in the IFU? How did you define that as

medical director?

A. Well, it would either need to have a frequency or a severity that had some implication for a risk/benefit ratio.

Q. Okay.

If a complication met that standard, it needed to be called out in the IFU. Right?

A. Yes.

Q. And if it was not -- rephrase.

And if a complication that met that standard was not included in the IFU, the IFU would be deficient by definition. Correct?

MR. GAGE: Objection.

THE WITNESS: I think it has to be based on the information you have at the time the IFU is created, so it will always evolve.

BY MR. SLATER:

Q. The information Ethicon had about the complications and risks from the Prolift® evolved over the years. Right?

A. Yes.

Q. That evolution was actually fairly significant as more and more procedures were done and Ethicon saw more clinical studies. Right?

MR. GAGE: Objection.

Exhibit D

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
ATLANTIC COUNTY
MASTER CASE 6341-10
CASE NO. 291 CT

- - -

IN RE:
PELVIC MESH/GYNECARE
LITIGATION

- - -

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

Friday, December 20, 2013
VOLUME III

- - -

Continued videotaped deposition of JAMES C. HART, M.D., held at RIKER DANZIG, SCHERER, HYLAND & PERRETTI, L.L.P., Headquarters Plaza, One Speedwell Avenue, Morristown, New Jersey, commencing at approximately 9:54 a.m., before Rosemary Locklear, a Registered Professional Reporter, Certified Realtime Reporter, Certified Court Reporter (NJ License No. 30XI00171000), and Notary Public.

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Q. And the purpose of the IFU is to provide a surgeon, for example -- well, rephrase.

And the purpose of the IFU is to provide a complete statement of what the company knows with regard to the indications, the contraindications, the warnings, the precautions and the adverse reactions for the device; correct?

A. Correct.

Q. Therefore, if your company, your medical affairs people, knew that using a cough test and local anesthesia would have a material impact on the efficacy that could be expected with the use of the TVT, that needed to be warned about in the IFU; correct?

MR. SNELL: Form.

Go ahead.

THE WITNESS: It -- it needed to be -- that information should be provided as training for the surgeon and an IFU is a place where it could go, yeah.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. The answer to my question is, if what I just asked you is accurate, that information needs to be in the IFU; correct?

Exhibit E

- - -

	:SUPERIOR COURT OF
	:NEW JERSEY
IN RE:	:LAW DIVISION -
PELVIC MESH/GYNECARE	:ATLANTIC COUNTY
LITIGATION	:
	:MASTER CASE 6341-10
	:
	:CASE NO. 291 CT

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF CONFIDENTIALITY

- - -

May 18, 2012

- - -

Transcript of the deposition of SEAN M. O'BRYAN, called for Videotaped Examination in the above-captioned matter, said deposition taken pursuant to Superior Court Rules of Practice and Procedure by and before Maryellen Coughlin, a Certified Realtime Reporter, Registered Professional Reporter, and Notary Public for the Commonwealth of Massachusetts, at the offices of Campbell Campbell Edwards & Conroy, P.C., One Constitution Center, 3rd Floor, Boston, Massachusetts, commencing at 10:05 a.m.

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warnings that a patient could be faced with that are important for the patient.

Q. And to the extent you had input into the Prolift® IFU drafting process, you certainly wanted to make sure that any warnings of any significant potential risks would be explicitly communicated to the intended or foreseeable users of the Prolift®, correct?

MS. KABBASH: Objection.

A. Sure. I rely on the medical team to tell me what is significant and what is important to convey into the instructions for use, package insert.

Q. When you worked on that project, it was your understanding from an FDA regulatory perspective it would not be legitimate to not include warnings of potentially significant adverse events based on a decision that the surgeons would figure that out on their own?

MS. KABBASH: Objection.

A. No, that's correct.

Q. Would you turn to Page 22, please. It's Paragraph D, D.1.3. The question is asked, "Do the results of the design validation performed as a result of this change in materials